K090597

Pascal Company, Inc.

MAR 16 2009

510(k) Summary (as required by section 807.92c)

Reference
Premarket Approval Number: *K030488*
Trade/Device Name: *Fluorilaq Sodium Fluoride Cavity Varnish*
Date of Concurrence: *May 2, 2003*

Submitted by	Vincent M. Tentarelli Pascal Company, Inc. 2929 NE Northup Way Bellevue, WA 98004 USA
Establishment Registration No.	3011632
Date Prepared	March 4, 2009
Device Trade Name	Fluorilaq Sodium Fluoride Cavity Varnish
Regulation Number	21 CFR 872.3260
Device Common Name	Dental Varnish
Regulatory Name	Cavity Varnish
Regulatory Class	Class II
Product Code	LBH
Substantial Equivalence	The modified varnish has the following similarities to that which previously received 510(k) concurrence: • Has the same active ingredient at the same concentration; • has the same indications for use; • incorporate the same or similar materials; • has the same shelf life, and; • is packaged using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2009

Mr. Vincent M. Tentarelli
Quality Assurance Manager
Pascal Company, Incorporated
2929 North East Northup Way
Bellevue, Washington 98004

Re: K090597
Trade/Device Name: Fluorilaq Sodium Fluoride Cavity Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Codes: LBH
Dated: March 4, 2009
Received: March 5, 2009

Dear Mr. Tentarelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Pascal Company, Inc.

Attachment 2: Indications for Use Statement

Reference
Premarket Approval Number: *K030488*
Trade/Device Name: *Fluorilaq Sodium Fluoride Cavity Varnish*
Date of Concurrence: *May 2, 2003*

510(k) Number (if known): K090597

Device Name: Fluorilaq Sodium Fluoride Cavity Varnish

Indications for Use:
Intended for use as a varnish on sensitive teeth over exposed dentin under temporary restoratives and cements where post-operative sensitivity is a concern and to improve quality and functionality of restorations when used in conjunction with dental restoratives and cements. To seal dentinal tubules in cavity preparations or on sensitive root surfaces.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

Kevin Mulvey-Sr MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090597